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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/092,297	06/05/1998	PATRICIA A. BILLING-MEDEL	6107.US.P1-0	5922

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EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/12/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/092,297

Applicant(s)
Billing-Medel

Examiner
Sharon L. Turner, Ph.D.

Art Unit
1647



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-22-00
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-55 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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Continued Prosecution Application

1. The request filed on 8-2-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/092,297 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 1-55 are pending.

Improper Markush

3. Prior to setting forth the restriction requirement, it is pointed out that applicants have presented instant claims in improper Markush format, see Ex parte Markush, 1925 C.D. 126, In re Weber, 198 USPQ 334 and MPEP 803.02 and 806.04. The claims are improperly set forth as the genus claims encompassing multiple products, as identified and claimed, fail to share the characteristics of a genus, i.e., a common utility and a substantial structural feature essential to the disclosed utility. Alternatively, the claims define multiple structurally distinct compounds capable of different use, with different modes of operation, different function and different effects. A reference against one of the claimed components or methods would not be a reference against the other. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims define inventions which are not proper species.

Election/Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- I. Claims 1-9, 40-42, and 45-55, drawn to methods of detecting target B-127 polynucleotides, classified in class 435, subclass 6.
- II. Claims 10-16, 25, 30, 33, 35, 38 and 39, drawn to polynucleotides, host cells, methods of producing the protein and kits, classified in class 536, subclass 23.1.
- III. Claims 17-19, 21, 22, 34, 36 and 37, drawn to polypeptides and kits, classified in class 530, subclass 350.
- IV. Claims 20 and 23-24, drawn to antibodies and kits, classified in class 530, subclass 387.1.
- V. Claims 26, 27 and 43, drawn to methods of using the antibody for detection, classified in class 435, subclass 7.1.
- VI. Claims 28, 29 and 44, drawn to methods of using the protein to detect, classified in class 436, subclass 518.
- VII. Claim 31, drawn to methods of making the antibody with protein, classified in class 514, subclass 2.
- VIII. Claim 32, drawn to methods of making the antibody with nucleic acid, classified in class 514, subclass 44.

5. The inventions are distinct, each from the other because of the following reasons:

6. Inventions II and I, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §

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806.05(h)). In the instant case the polynucleotides can be used in transformation of cells, gene therapy, chromosomal mapping and for producing protein.

7. Inventions III and VI, VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be labeled and used for detection of antibodies, as an immunogen or as a therapeutic.

8. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used as a therapeutic or as a means for purification.

9. Inventions IV and VII, VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody may be made by administration in vivo, by transformed B-cells or by using a recombinant plasmid.

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10. Inventions II, III and IV are related as products. The products are distinct each from the other as they are alternatively composed of unique nucleic acid and peptide sequences and differ in secondary and tertiary structure.

11. Inventions I, V, VI, VII and VIII are related as methods. The methods are distinct as they differ in reagents, steps and outcomes.

12. Furthermore, in addition to the election of one of the above VIII groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

A) A single designated nucleic acid composition selected from SEQ ID Nos: 1-5.

B) A single polypeptide or antibody reactive to the peptides selected from SEQ ID

NO:17-20.

13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

14. Because these inventions are distinct for the reasons given above and the search required for any Group is not required for any other Group, restriction for examination purposes as indicated is proper.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

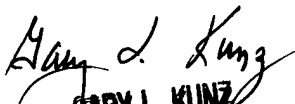
17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973.

Sharon L. Turner, Ph.D.
June 6, 2002


GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600